510(k) Summary

for

Derma Sciences Medihoney Dressings APR 2 3 2008 with Active Manuka Honey

1. Sponsor

Derma Sciences 214 Carnegie Center Suite 100 Princeton, NJ 08540

Contact Person: Barry Wolfenson

Derma Sciences

214 Carnegie Center, Suite 100

Princeton, NJ 08540

Telephone: 609.514.4744 x1103

Date Prepared: April 2, 2008

2. DEVICE NAME

Proprietary Name:

Derma Sciences Medihoney Dressing with Active Manuka

Honey

Common/Usual Name:

Wound Dressing

Classification Name:

Dressing

3. PREDICATE DEVICES

- Medihoney Primary Wound Dressings with Active Manuka Honey (K072956)
- API-MED Active Manuka Honey Wound Dressings (K053095)

4. DEVICE DESCRIPTION

Derma Sciences Medihoney Dressing with Active Manuka Honey are sterile, wound care dressings for use in moist wound management. The Derma Sciences Medihoney Dressing with Active Manuka Honey are offered in several sizes including .5, 1, and 1.5 oz. sizes.

The proposed Medihoney Dressing with Active Manuka Honey contains Active Manuka Honey. As wound exudate is absorbed, the alginate forms a gel, which assists in maintaining a moist environment that aids supports the autolytic debridement for optimal wound healing.

5. INTENDED USE

The Derma Sciences Honey Wound Dressings provide a moist environment conducive to wound healing and is indicated for the management of light to moderately wounds such as:

- diabetic foot ulcers
- leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
- pressure ulcers / sores (partial and full thickness)
- 1st and 2nd degree partial thickness burns
- donor sites, and traumatic and surgical wounds.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Derma Sciences Honey Wound Dressings are essentially identical to the parent Medihoney Primary Wound Dressings with Active Manuka Honey subject of K072956 and API-MED Active Manuka Honey Wound Dressings subject of K053095. The differences between the Derma Sciences Medihoney Dressings with Active Manuka Honey and the predicate devices are limited to a slight formulation change.

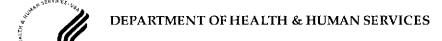
The technological characteristics of the Derma Sciences Medihoney Dressings with Active Manuka Honey, the parent Medihoney Primary Dressings and the API-MED Active Manuka Honey Wound Dressings are substantially equivalent in that they are all dressings suitable for use on pressure sores, leg ulcers, post-operative wounds, superficial wounds and abrasions.

The modifications made to the Medihoney Primary Dressings with Active Manuka Honey to produce the Derma Sciences Medihoney Dressings with Active Manuka Honey are limited to a slight change in formulation. The proposed Medihoney Honey Wound Dressings are comprised of 100% w/w of Active Manuka Honey and the predicate API-MED Active Manuka Honey Dressings are comprised of 95% Active Manuka Honey and 5% calcium alginate. This slight change in formulation simply provides the user with a wider variety of honey dressings and does not represent a

significant change in technological characteristics of the Medihoney Primary Dressings with Active Manuka Honey. The only differences between the Derma Sciences Medihoney Dressing with Active Manuka Honey and the predicate devices include slightly different dressing composition which are minor and do not affect the safety and effectiveness of the device.

7. Performance Testing

Biocompatibility testing performed to support the formulation change for the modified dressings demonstrates that the Medihoney Dressing with Active Manuka Honey are safe for their intended use. Sensitization, and irritation testing was performed successfully using the Derma Sciences Wound Dressings. Cytotoxicity Testing using the 100% honey Medihoney Dressings demonstrated a moderate cytotoxic reaction. This reaction is expected since in research work performed, it has been found that the maximum concentration of honey that can be tolerated using cells in culture is about 2%. This is due to the osmotic effect which is the same effect as would be seen in a solution of sugars as in honey. However, neither sugar nor honey used on open wounds causes any adverse effects. In anticipation of this reaction using the Medihoney Wound dressings, Derma Sciences has initiated implantation testing to support the safe use of these dressings. This testing showed that the macroscopic reaction was not significant as compared to the control material and slight compared to the negative control implant material. Microscopically, the Medihoney Dressing was classified as a non irritant as compared to the control article and a slight irritant compared to the negative control article.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

APR 23 2008

Derma Sciences, Inc.
% Medical Device Consultants, Inc.
Mary McNamara-Cullinane, RAC
Senior Regulatory Consultant
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K080315

Trade/Device Name: Derma Sciences Medihoney Dressings with Active Manuka Honey

Regulatory Class: Unclassified

Product Code: FRO Dated: April 4, 2008 Received: April 7, 2008

Dear Mr. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mary McNamara-Cullinane, RAC

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark of Melkers

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K080315

Device Name:

Derma Sciences Medihoney Dressings with Active Manuka

Honey

Indications for Use:

The Derma Sciences Medihoney Dressings with Active Manuka Honey provide a moist environment conducive to wound healing and is indicated for the management of light to moderately exuding wounds such as:

- · diabetic foot ulcers
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- 1st and 2nd degree partial thickness burns
- donor sites, and traumatic and surgical wounds.

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use ____(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number <u>K090315</u>